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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/529,715	04/19/00	OHASHI M	2000-0486A

EXAMINER	
GOLAMIDI,S	
ART UNIT	**PAPER NUMBER**
1616	5

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DATE MAILED: 08/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/529,715	OHASHI ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Receipt has acknowledged the preliminary amendment request.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Negoro et al (5258382). Negoro et al discloses the instantly claimed aldose reductase in a pharmaceutical composition (see abstract and col 4, line 39). Negoro et al disclose the aldose reductase inhibitor (1%) with a diluent (73%), a binder (3%), a lubricant (1%), and disintegrator (22%) (see example 29). Since "fast" is a relative term, the reference meets the requirements of instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al in view of Bavitiz et al (4910022) and vice versa.

Negoro et al teach the instantly claimed aldose reductase inhibitor compound in a pharmaceutical composition for the treatment of diabetes (see abstract). The reference discloses the aldose reductase inhibitor (1%) with a diluent (73%), a binder (3%), a lubricant (1%), and disintegrator (22%) (see example 29). However, Negoro et al does not teach the rapid dissolution of the composition with claimed release rates.

Bavitz et al teach an aldose reductase in fine granules incorporated in a pharmaceutical composition for treating diabetes (see abstract). The reference teaches the use of diluents (8-20%), binders (1-4%), lubricants (.5-2%), and disintegrators (1-4%) with the aldose reductase (83-88%) (col 2, lines 22-28). The reference teaches rapid dissolution of the composition and gives dissolution percents after for 10, 15, 20, 30, 45, and 60 minutes. After 15 minutes the 77% of the composition is dissolved, the instant claim of 80% is close to the range of the prior art and is deemed obvious to one of ordinary skill in the art at the time the invention to manipulate the conditions to obtain the best possible results. Further, Bavitz et al suggest several particle sizes for the aldose reductase in the examples. The reference describes passing the aldose granules in sieves of certain sizes, indicative of the maximum particle size used. Therefore, it is deemed obvious of one of ordinary skill in the art at the time the invention was made to manipulate the particle size to obtain the optimum particle through routine experimentation.

Bavitz et al lacks the teaching of the instantly claimed aldose reductase inhibitor.

It would have been obvious to use the fast dissolution formulations of Bavitz et al for the aldose reductase inhibitor taught by Negoro et al since both formulations are

drawn to aldose reductase inhibitors for the treatment of diabetes. Since Bavitz et al teach that the formulation has to have the appropriate physiochemical properties for the effective and efficient utilization of the drug, such as rapid disintegration and dissolution (col1, 55-58).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the aldose reductase inhibitor of Negoro et al in the rapidly dissolving formulation of Bavitz et al because both are for the treatment of diabetes using aldose reductase inhibitors and Negoro et al teach that the claimed compound (AS-3201) has superior aldose reductase inhibitory activity with less toxicity (col 2, lines 51-55).

One of ordinary skill in the art at the time the invention was made would be motivated to combine the teachings of both references to yield a low toxic, rapid dissolving drug composition for the treatment of diabetes.

Claims 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Negoro et al in view of Bavitz et al or vice versa as set forth above, in further view of Ikeda et al (5952356). Negoro et al and Bavitz et al disclose an aldose reductase in a pharmaceutical composition. The references do not teach the use of an acidic substance such as citric acid. Ikeda et al teach the routine use of acids such as citric acid as pH control agents, in their pharmaceutical composition to treat diabetes (col 14, lines 41-45).

It is obvious to one of ordinary skill at the time the invention was made to use Ikeda et al's acids to provide the composition with a desired pH.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616